Study to determine the 99th percentile upper reference limit (URL) for the Minicare Cardiac Troponin (cTn-I) testing device in male and female adults

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON42657

Source
ToetsingOnline

Brief title
Minicare cTn-I system study

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Philips Electronics Nederland B.V. Philips Handheld Diagnostics

Source(s) of monetary or material Support: Andere industrie

Intervention

Keyword: Minicare, troponine

Outcome measures

Primary outcome

To determine the 99th percentile URL of the Minicare cardiac troponin-I (cTn-I)

system in healthy male and female adults according to clinical laboratory

standards institute (CLSI) C28 A3 recommendations.

Secondary outcome

NA

Study description

Background summary

The Minicare cTn-I system is a new device that is developed for the diagnostics of myocardial infarction. The device measures a protein called cardiac troponin I (cTn I) in a blood sample. Troponins are proteins that are part of cardiac cells and skeletal muscle cells. There are 3 types of troponins: troponin I, troponin T, and troponin C. From these troponins, cardiac troponin-I (cTn-I) is the only type that is unique for myocardia tissue. In general, cTn-I is present at very low levels in the blood of healthy subjects. However, in patients with myocardial infarction, heart muscle cells get damaged. As a result cTn-I may enter the blood stream and values increase rapidly. Nowadays, measurement of cTn-I levels in blood is accepted as the standard laboratory test for the diagnosis of myocardial infarction.

Study objective

In the current study a normal reference value for cTn-I in blood from healthy adults will be determined and will be measured with the new device. This reference range is age-dependent. To measure the normal values per age group, blood samples will be taken from 700 healthy adults (about 350 males and 350 females). The concentration of cTn-I in blood will be measured by using the newly developed Minicare cTn-I system. The Minicare cTn-I system is a small

user-friendly portable apparatus to measure cTn-I levels in blood within minutes. The measurement is based on nanotechnology (www.philips.com/minicare).

This study is not intended to improve your health, but is necessary to determine the normal cTn-I values in blood of healthy volunteers. These values are critical to be able to discriminate between healthy and elevated values of cTn-I when using the Minicare cTn-I system.

Study design

For this study the volunteer will need to bring a valid proof of identity (passport, driving license, residence permit or ID card). Upon arrival to the research center the volunteer will undergo a short screening procedure during which the volunteer will be asked to complete a questionnaire about his/her health conditions. If the volunteer is considered eligible for this study based on the questionnaire, 3 small blood samples will be taken and one finger prick will be done. Two blood samples will be used to check if the blood is suitable for the test. The other sample will be used for the test on the Minicare cTn-I system. The volunteer can leave the research center after the blood draw. The total length of the study will be less than 2 hours.

Study burden and risks

A venipuncture is a standard procedure to collect blood. The venipuncture and finger prick may be painful and may also cause a light bleeding or a bruise. No other adverse effects are to be expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy male and female subjects
*18 years old

Exclusion criteria

1. Personal history of AMI or other cardiac diseases (MI, angina, stroke, atrial fibrillation, peripheral vascular disease (PVD), deep vein thrombosis (DVT), pulmonary embolism (PE), cardiac valve disease, heart failure), chronic obstructive pulmonary disease (COPD), immunological disease (eg. systemic lupus erythematosis [SLE] and reumatoid arthritis), diabetes mellitus, hypertension (except for subjects *70 years on stable medication for hypertension and normal/stabilized blood pressure) or drug-of-abuse (based on questionnaire)
2. History of cancer in last 5 years (evaluation through questionnaire).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2015
Enrollment:	850
Type:	Actual

Ethics review

Approved WMO Date:	02-04-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-11-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL52805.056.15